

### **REMARKS**

Claims 126-145 were pending in the present application. Applicants have amended claim 128 to change its formality and canceled claim 127 without prejudice. Applicants respectfully submit that the present Amendment is fully supported by the original specification and does not raise any issue of new matter. Therefore, entry of the present Amendment is respectfully requested. Upon entry of the present Amendment, claims 126, 128-145 will be under examination.

### **REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 126-145 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement insofar as the claimed pharmaceutical composition reads on an aqueous composition.

Applicants respectfully point out that the azithromycin in the claimed pharmaceutical composition is crystalline (emphasis added) azithromycin monohydrate hemi-ethanol solvate and therefore, the claims cannot be interpreted to cover pharmaceutical compositions where azithromycin monohydrate hemi-ethanol solvate is dissolved into a solution and lose its crystal structure. Applicants note that the present response will form part of the prosecution history for the present application and the statements in the present Amendment will be used to aid the proper interpretation the scope of the claims. With such a clear and unambiguous statement from Applicants on the scope of the claims, the currently pending claims can only be interpreted as not covering a solution of azithromycin monohydrate hemi-ethanol solvate. Therefore, this ground of rejection is moot as the full scope of the pending claims, as properly interpreted, are fully enabled.

### **REJECTION UNDER 35 U.S.C. §102(b) & §103(a)**

Claims 126-145 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bright, U.S. Patent No. 4,474,768 (hereinafter "Bright").

Applicants respectfully disagree with this ground of rejection for the same reasons as stated in Applicants' response to the rejection under 35 U.S.C. §112, first paragraph.

Applicants respectfully submit that the currently pending claims, when properly

construed in view of the file history which includes the present Amendment, would not cover pharmaceutical compositions where the substantially pure azithromycin monohydrate hemi-ethanol solvate is dissolved into a solution and lose its crystal structure. Therefore, this ground of rejection is moot. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

REJECTION UNDER 35 U.S.C. §102(a)

Claims 126-145 stand rejected under 35 U.S.C. §102(a) as allegedly anticipated by Singer et al., U.S. Patent No. 6,365,574 (hereinafter "Singer").

Applicants respectfully point out that Singer is not a proper reference against the present application. Applicants note that Singer has a publication date of April 2, 2002 and present application has an earliest priority date of May 22, 2001, i.e., the filing date of U.S. Provisional Application No. 60/292,565.

In addition, as shown in the July 13, 2005 declaration from Dr. Todd Darrington (attached herein), Applicants had reduced the claimed invention to practice prior to May 8, 1998, before the April 2, 2002 publication date of Singer. Therefore, this ground of rejection is moot. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

### CONCLUSION

In view of the claim amendments and the remarks, further and favorable consideration of all pending claims and the issuance of a Notice of Allowance with respect to all pending claims are respectfully requested.

It is believed that no fee is deemed necessary in connection with the filing of the present Amendment. However, if any fees are required, the Commissioner is hereby authorized to charge any such fees to our Deposit Account No. 16-1445.

Respectfully submitted,

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Lance Y. Liu

Lance Y. Liu  
Attorney for Applicant(s)  
Reg. No. 45,379

**Customer No. 28523**

Pfizer Inc.  
Patent Department, MS 8260-1611  
Eastern Point Road  
Groton, Connecticut 06340  
(860) 686-1652